

REMARKS

In the Office Action, the title has been objected to; Claims 6 and 23-24 have been rejected under 35 U.S.C. §112; Claim 6 has been rejected under 35 U.S.C. §102; and Claims 6 and 22-24 have been rejected under 35 U.S.C. §103. Claim 6 has been amended. Applicants believe that the rejections should be overcome in view of the amendment and at least for the reason set forth below.

At the outset, the Patent Office appears to object to the title of the invention as allegedly not descriptive. As presently pending, the title recites a method for increasing insulin sensitivity. As the pending claims are directed to a method for increasing insulin sensitivity in a mammal. Applicants believe that the title is sufficiently descriptive of the claimed subject matter. Therefore, Applicants respectfully request that this objection be withdrawn. If the Patent Office's position is still maintained, Applicants respectfully request that the Patent Office suggest a title that is deemed to be descriptive of the claimed subject matter for further consideration.

In the Office Action, Claims 6 and 23-24 are rejected under 35 U.S.C. §112, first and second paragraphs. As previously provided, sole independent Claim 6 has been amended to recite a method for increasing insulin sensitivity in a mammal. The method includes selectively increasing production of propionate in a gastro-intestinal tract of the mammal by orally administering a nutritional composition comprising dextran having a molecular weight above about 500, wherein dextran is administered in an amount from about 2 g per day to about 15g per day. Applicants believe that the rejections pursuant to 35 U.S.C. §112 should be withdrawn in view of same and as discussed in further detail below.

With respect to the rejection pursuant to 35 U.S.C. §112, second paragraph, the Patent Office alleges that there is no clear nexus between the process intended to be performed as outlined in the preamble and the body of the claim. See, Office Action, page 3. As previously provided, the method of Claim 6 includes, in part, selectively increasing production of propionate in a gastro-intestinal tract by the oral administration of dextran as further claimed. Thus, this should clarify that an increase in insulin sensitivity can be obtained by selectively increasing production of propionate through the oral administration of dextran in specified amounts as claimed.

The oral administration of dextran in specified amounts as claimed is clearly supported in the specification, for example, in example 3. In this example, the volunteers were given an acute dose of 15g of dextran T 2000 and a chronic dose of 10g of dextran T 2000 per day. See, Specification, page 8, line 11-16. The results indicated that an increase in the level of propionate acid in the gastro-intestinal tract followed consumption of dextran in these amounts. See, Specification, page 9, lines 5-6.

With this increase, one skilled in the art would readily understand that an increase in insulin sensitivity would also result where insulin sensitivity is generally recognized and accepted as a measure for the effectiveness of removing glucose from the blood stream. As detailed further in the present application, propionate can enhance glycolysis and can inhibit gluconeogenesis which are both clear indicators of low blood glucose levels, thus again demonstrating the impact of propionate on glucose metabolism. As insulin is the only known molecule lowering blood glucose elevation, propionate may indirectly trigger a more effective way of absorbing glucose from the blood, and thus enhancing/increasing insulin sensitivity, which in turn may reasonably be understood as having an effect of lowering glucose levels of the blood. See, specification, for example, p. 1, lines 21-33. In view of same, Applicants believe that the subject matter as claimed is sufficiently clear in scope and meaning such that one skilled in the art would readily be able to practice the claimed invention and further readily understand and recognize that the claimed invention was in possession of the inventors at the time the application was filed.

Accordingly, Applicants respectfully request that the rejections pursuant to 35 U.S.C. §112, first and second paragraphs, be withdrawn.

In the Office Action, Claim 6 is rejected under 35 U.S.C. §102 as allegedly anticipated by European Patent Document No. 0153013 ("ALSOP"). At the outset, Applicants believe that this rejection is improper based on the fact that the Patent Office again rejects Claim 6 for alleged obviousness reasons in view of ALSOP in addition to another reference. See, Office Action, page 8. Indeed, Claim 6 is directed to a method of increasing insulin sensitivity where the Patent Office appears to have relied on a secondary reference for its alleged teaching regarding increasing insulin sensitivity to further support ALSOP. Therefore, Applicants believe that the

anticipation rejection in view of ALSOP is improper and should be withdrawn for at least this reason.

Further, Claim 6 has been amended to recite that dextran is orally administered in an amount from about 10g per day to about 15g per day. This clearly contrasts ALSOP where the Patent Office has indicated that dextran is provided in a formulation in an amount of 2.5g/l which is presumed to be administered once a day. Therefore, Applicants believe that ALSOP fails to inherently and explicitly disclose a method for increasing insulin sensitivity as required by Claim 6 based on at least these reasons.

Accordingly, Applicants respectfully request that the anticipation rejection in view of ALSOP be withdrawn.

In the Office Action, Claims 6 and 22-24 are rejected under 35 U.S.C. §103 as allegedly unpatentable over ALSOP and European Patent Document No. 382355 ("Mitsuhashi"). As previously provided, Claim 6 has been amended to recite, in part, that dextran is orally administered in an amount that ranges from about 10g per day to about 15g per day to selectively increase propionate production thereby increasing insulin sensitivity. Nowhere does the cited art even if properly combinable disclose or suggest the claimed invention.

With respect to the ALSOP reference, indeed, the Patent Office even admits that ALSOP fails to recognize a method for increasing insulin sensitivity where it appears to have relied on Mitsuhashi to remedy this deficiency in ALSOP. Further, ALSOP fails to provide the oral administration of dextran in specified amounts as claimed, let alone to selectively increase propionate production as further claimed and previously discussed above. Therefore, ALSOP on its own is clearly distinguishable from the claimed invention.

Further, Applicants do not believe that Mitsuhashi can be relied on solely to remedy the deficiencies of ALSOP. For example, Mitsuhashi teaches that low molecular dextran allegedly promotes the growth of *Bifidobacteria* in the intestine, yet even fails to provide convincing data for demonstrating such an enhanced growth. Indeed, the cell counts were $9.9 \pm .4$ and 10.2 ± 0.4 before and after dextran administration, respectively, as disclosed in Table 1. In addition, Mitsuhashi merely suggests that low molecular dextran might have an effect with respect to the prevention of geriatric diseases, such as hypertension, diabetes, myocardial infraction and malignant tumors. See, Mitsuhashi, page 5, lines 39-43. This is purportedly due to a synthesis

of vitamins or a decrease in the intestinal pH level as further disclosed in Mitsuhashi at page 2, lines 12-20. Thus, the increase of insulin sensitivity cannot be derived from Mitsuhashi as it should be clear from Mitsuhashi that a prevention of diabetes may be obtained by various other effects, such as by weight reduction, as well as by vitamins or a decreased intestinal pH level as provided in Mitsuhashi and discussed above. Id.

Moreover, Mitsuhashi is specifically directed to *Bifdobacteria*, which bacteria according to Mitsuhashi produce organic acids, such as acetic acid and lactic acid, thus resulting in a decrease of the intestinal pH. See, Mitsuhashi, page 2, lines 12-13. Nowhere does Mitsuhashi relate to the production of propionic acid, let alone selectively increasing amounts thereof as claimed. Thus, clearly Mitsuhashi fails to disclose or suggest that an enteral administration of dextran in specified amounts as claimed can result in a selectively increased amount of propionic acid in the gastro-intestinal tract and, thus in a direct consequence therefrom, in an increased insulin sensitivity as required by the claimed invention.

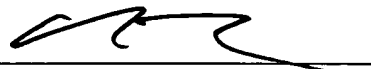
Indeed, Mitsuhashi effectively teaches away from an administration of dextran as Mitsuhashi provides that the administration of dextran correlates to an increased production of acetate (See, Mitsuhashi page 2, lines 12-13), thus resulting in increased plasma fatty acid concentrations (See, Specification, page 1, lines 26-27) at levels that should be considered by the skilled artisan as detrimental for any person and in particular for persons in need of food supplements for increasing insulin sensitivity. Based on at least these reasons, Applicants believe that one skilled in the art would not be inclined to modify ALSOP in view of Mitsuhashi to cover the claimed invention. Therefore, Applicants respectfully submit that ALSOP and Mitsuhashi even if properly combinable fail to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 6 and 22-24 be withdrawn. Applicants further note that Claim 22 has been canceled as indicated above and thus this rejection should be rendered moot with respect to same.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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